May 10, 1996

Dear Medical Physicist:

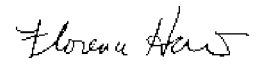
The enclosed document, **MEDICAL PHYSICIST'S ANNUAL SURVEY REQUIREMENTS**, is intended as guidance to medical physicists in mammography. The document outlines the responsibilities of the medical physicist under the Mammography Quality Standards Act (MQSA) of 1992 and describes what is required in the facility survey report under the interim regulations. It also lists the minimum qualifications that medical physicists must meet in order to conduct mammography surveys under MQSA.

If you would like copies of the *Federal Register* publications of December 21, 1993, or September 30, 1994 (MQSA interim rules and their amendments); the *Federal Register* of April 3, 1996 (MQSA proposed final rules); or *Mammography Matters* (FDA's newsletter on MQSA implementation), please send a FAX request to 301-986-8015 or write to:

MQSA
c/o SciComm, Inc.
P.O. Box 30224
Bethesda, MD 20824-9998

We at FDA are committed to work with you to improve the quality of mammography. If you have any questions regarding MQSA inspections, you may call 1-800-838-7715.

Sincerely yours,



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Enclosure

MEDICAL PHYSICIST'S ANNUAL SURVEY REQUIREMENTS

March 29, 1996

Division of Mammography Quality
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FDA/CDRH (HFZ-240)
1350 Piccard Drive
Rockville, MD 20850

MEDICAL PHYSICIST'S ANNUAL SURVEY REQUIREMENTS

March 29, 1996

CONTENTS

MEDICAL PHYSICIST'S ANNUAL SURVEY REQUIREMENTS

INTRODUCTION

The Mammography Quality Standards Act (MQSA) requires (e)(1)(B)(iv) "...as a condition of accreditation that each facility undergo a survey at least annually...to assure that the facility meets the standards..." and further that (f)(1)(F) "...a medical physicist...survey mammography equipment and oversee quality assurance practices at each facility." This survey (a)(7) "...means an onsite physics consultation and evaluation performed by a medical physicist..."

MQSA also states (g)(1)(C), "In conducting inspections... [the inspector] shall have access to all...materials, records, and information that the Secretary...considers necessary to determine whether the facility is being operated in accordance with this section."

MQSA inspectors are required to determine if an annual survey has been performed by a medical physicist and to review the report of the medical physicist's survey and other relevant material.

The Food and Drug Administration (FDA) published **Interim Regulations** under MQSA in the Federal Register on December 21, 1993 and September 30, 1994. These regulations require that 900.12(d)(5) "As part of its overall quality assurance program, each facility shall have a medical physicist establish, monitor and direct the procedures required...and perform a survey of the facility to assure that it meets the quality control and equipment standards..." The regulations further state that 900.12(d)(1) "...Such quality assurance program shall: (I) For screen-film systems, be substantially the same as that described in the 1992 or the 1994 edition of 'Mammography Quality Control: Radiologist's Manual, Radiologic Technologist's Manual, and Medical Physicist's Manual', prepared by the American College of Radiology..."

MQSA inspectors are required to determine not only if an annual survey has been performed by the medical physicist but also if that survey was "substantially the same as" that outlined in the ACR Manual. Where there are differences in the two editions of the manual, the medical physicist may follow either edition and is not required to meet the more recent (or the more stringent) of the two. However, FDA recommends that the more recent manual be followed.

In light of these requirements, the material that follows is designed to summarize what the Interim Regulations (through the adoption of the ACR manual) require with respect to the medical physicist's survey and what the MQSA inspectors will look for when reviewing the survey report during inspections (which will often be less than what is technically required).

In a number of instances we will also indicate what FDA "recommends" as distinct from what FDA "requires" under the Interim Regulations (or what the inspector will look for during inspections). **Please keep this distinction clearly in mind. Recommendations are simply that and are NOT requirements.**

To assist the reader in preparing for the survey, we have included in each section of this document, a printout of the inspection procedure computer screen(s) relevant to each part of the survey. These are the screens the inspectors use to enter data and answer questions during MQSA inspections.

In the data entry screens in this document, "**y**" refers to "yes", "**n**" refers to "no", "**c**" refers to "claimed" but no supporting documents are available at the time of the inspection, "**u**" refers to "unknown","**p**" indicates that the test was not done for all cases required, and "**x**" refers to "not applicable". A "y" answer implies compliance with the requirements, an "n" or a "p" answer will generate a noncompliance statement, and a "c" answer will generate a remark at the end of the inspection report to indicate that the facility owes the inspector missing documents that need to be provided expeditiously. Neither "x" nor "u" will generate a noncompliance statement.

FDA has assigned three noncompliance levels which are briefly defined below:

Level 1. Level 1 is the most serious. It indicates a failure to meet a key MQSA requirement that may compromise the quality of mammography services performed at the facility. Each Level 1 finding is carefully reviewed by the FDA, and if confirmed, the facility will receive a Warning Letter requiring a response within 15 days regarding the necessary corrective action(s).

Level 2. In the absence of Level 1 findings, a Level 2 finding indicates that the facility meets all key MQSA requirements but fails to meet a significant mammography quality item. This usually requires a response from the facility within 30 days regarding the necessary corrective action(s).

Level 3. In the absence of Level 1 and Level 2 findings, Level 3 findings indicate that the facility meets all major MQSA requirements with only minor problems. While the facility is expected to correct **all** noncompliances found during an MQSA inspection as soon as possible regardless of their levels, it is not required to send a written response to the FDA concerning Level 3 noncompliances. Corrective actions regarding these are usually checked during the next annual inspection.

Currently, the first occurrence for almost all of the noncompliances associated with the survey report is classified as a Level 3 noncompliance. The only exceptions are:

Level 1 - Conduct of a mammography survey by an unqualified medical physicist.
- Clinical use (in a fully accredited and certified facility,) of an x-ray unit for which no survey has been conducted.

Level 2 - Clinical use of an x-ray unit whose most recent survey date exceeds 14 months.

GENERAL

Does the survey meet the requirement that it be conducted at least annually?

The Act and the Interim Regulations make it clear that the medical physicist's survey must be conducted **at least** annually. MQSA inspectors are currently required to determine if at least the annual requirement is met by noting if, at the time of the inspection, the most recent survey is 14 months old or less. This approach was selected to provide facilities and physicists some flexibility in scheduling the surveys. This requirement means that the date of the survey must be indicated in the survey report or in an accompanying cover sheet, letter, etc. Physicists and facilities even have the option of conducting the survey in a "piecemeal" fashion rather than all at once. MQSA requires that no part of the survey (no test or review) be more than 14 months old at the time of the inspection. If the survey is conducted in this fashion, then each part of the survey must contain the date on which it was conducted.

Is the survey complete?

The Medical Physicist's section of the ACR Manual [adopted by reference in the MQSA Interim Regulations] contains "detailed procedures for a number of tests designed to be conducted at least annually...to assess the continuing performance of mammographic equipment" (p1 1992, p133 1994). These tests represent "the minimum set of tests that should be conducted on an annual basis..." MQSA inspectors are required to determine if this minimum set of tests (10 in all) has been conducted as part of the survey. Further, the "tests should be performed at technique factors used clinically for mammography." FDA interprets this to mean techniques used clinically **in the particular facility** rather than in general; and for appropriate tests the MQSA inspectors are required to determine if the tests were in fact conducted at the appropriate clinical techniques (see details in the discussion of each test below).

Are the results of the survey communicated accurately to the facility?

The manual also states (p1 1992, p133 1994) that, " It is the responsibility of the medical physicist conducting these tests to accurately convey test results in a written report, to make recommendations for corrective actions according to the test results, and to review the results with the radiologist and the QC technologist." The manual further states (p2 1992, p134 1994), "To assist the physicist in communicating test results and recommendations, Summary Forms have been included... These forms should be used or appropriately modified to summarize the results and recommendations of the medical physicist's QC testing and surveys." MQSA inspectors are required to review the report of the survey and determine if it is adequate to meet these requirements.

The inspector will determine if there is a clear indication of whether each test or review (in the case of the technologist QC test review) passed or failed and, in appropriate cases (see specific sections below), that the numerical results of the tests (such as C.O.V. for accuracy and reproducibility, HVL value, dose value, etc..) are provided to the facility. FDA recommends the

physicist also provide the raw data obtained during the survey measurements and which are subsequently used to determine whether each test had passed or failed.

Further, the inspector will determine if the report contains a summary of the findings, as well as recommendations when the findings indicate that one or more of the tests or reviews have not "passed." This summary need not be on the forms in the manual but could simply be text in a cover letter to the report.

The manual also states (p1 1992, p133 1994), "Corrective actions should not be limited to repair of x-ray equipment by a qualified service person, but should include recommendations that might improve image quality, including recommendations concerning image receptors, technique factors, processing, viewing conditions and quality control." The presence or absence of such recommendations is NOT currently addressed during MQSA inspections.

Is the report signed?

Both the Act and the Interim Regulations require that the survey be conducted by a medical physicist who meets specific qualification requirements. MQSA inspectors are currently required to determine if the report of the annual survey is signed by (or contains the identification of) the same medical physicist who conducted or directly supervised the conduct of the survey. Direct supervision means that the qualified physicist is present in the test room during the survey. **It is that medical physicist whose qualifications will be assessed during the inspection**.

It is not a requirement that the report contain a handwritten signature, but rather that the report indicate, at a minimum, the last name and first initial of the fully qualified medical physicist who conducted the survey. If other personnel assisted in the conduct of the survey, for training purposes or otherwise, their names may be indicated in the report, but this is NOT a requirement.

Inspection questions and entries relating to general survey information are listed in screen #1 below:

Screen #1

?44**Survey/Report Information**444@
Has a survey been done? (y/n/c)
Survey Date mm/dd/yy
Report Date mm/dd/yy
Report Contains Summary? (y/n/x)
Recommendations? (y/n/x)
Report Signed? (y/n/x)
Signed by ---------
Remarks
B4444444444444444444444444444444444A
<F2> = LOOKUP for Codes:

EVALUATION OF THE TECHNOLOGIST'S QC PROGRAM

The medical physicist's section of the ACR manual (Introduction and Appendix 1) states that:

1) "The medical physicist should periodically review the results of the routine quality control tests

   conducted by the QC technologist and make recommendations regarding these tests," (p1 1992, p133 1994).

2) "The physicist should check that QC tests are properly performed and documented and that appropriate actions are being taken to correct problems when they occur," (p49 1992, p183 1994).

3) "The medical physicist should review the QC/QA Procedures Manual on each visit to a site, reviewing contents to ensure that the manual is up-to-date and contains at least a summary of the last year's tests," (p49 1992, p183 1994).

4) "The medical physicist may wish to provide an independent verification that the processor is functioning properly for mammography," (p49 1992, p183 1994).

5) "The medical physicist can also provide a useful independent check of darkroom cleanliness, proper safelight and filter, light leaks, fog levels, and film viewing conditions," (p50 1992, p184 1994).

6) "Problems with the mammography site's quality and QC program and recommendations to the site for improvement should be clearly communicated in a cover letter or summary sheet of Problems and Recommendations," (p50 1992, p184 1994).

MQSA inspectors are currently required to determine only if the survey report contains the results of the medical physicist's assessment of each of the 11 tests and tasks that make up the required technologist QC program (item 1 above). It is presumed that problems detected with the performance and/or documentation of these tests and tasks (item 2 above) would result in recommendations outlined in the report (item 6 above). The other requirement (item 3 above) and the recommendations (items 4 and 5 above) are not addressed during current MQSA

inspections. Inspection questions and entries relating to evaluation of the technologist QC program are listed in screen #2 below:

Screen #2

444444**Physicist's Evaluation of Technologist's QC Tests**444444@

Darkroom cleanliness?	(y/n/x)
Processor QC?	(y/n/x)
Screen cleanliness?	(y/n/x)
View boxes and viewing conditions?	(y/n/x)
Phantom image?	(y/n)
Visual checklist?	(y/n)
Repeat analysis?	(y/n/x)
Analysis of fixer retention?	(y/n/x)
Darkroom fog?	(y/n/x)
Screen-film contact?	(y/n/x)
Compression?	(y/n)

Remarks

B4444444444444444444444444444444444444444444444444444444444444444444444444A

<F2> = LOOKUP for Codes: <F9> to edit remark.

Note: The x's in the previous screen are used when evaluating a survey of a second or subsequent x-ray unit.

THE PHYSICIST'S 10 QC TESTS

It is assumed that, except for surveys of new machines in new facilities, the kVp normally used clinically by the facility (the most commonly used kVp) is known at the time the survey is conducted. Therefore, the physicist must use that value (±1 kVp) where applicable throughout these tests. If that value is not yet established at the time of the survey, a best-guess value is acceptable.

1. Mammographic Unit Assembly Evaluation

The ACR manual requires that the physicist check a number of mechanical items on the x-ray unit. While seven items are listed (p3 1992, p135 1994), the forms provided in the manual split one of these items into two and add two additional items: one on technique charts and the other on radiation shielding, making a total of ten items (p63 1992, p197 1994). MQSA inspectors are currently required to review the survey report to determine if the medical physicist checked each of the 10 items.

Inspection questions and entries relating to x-ray system assembly evaluation are listed in screen #3 below:

Screen #3

?4444444444444444444**X-Ray System Assembly**44444444444444444444444444
Free standing dedicated unit is mechanically stable? (y/n)
All moving parts move smoothly, without obstruction? (y/n)
All locks and detents work properly? (y/n)
Image receptor holder assembly is free from vibrations? (y/n)
Image receptor is held securely in any orientation? (y/n)
Image Receptor slides smoothly into holder? (y/n)
Compressed breast thickness scale accurate to +/- 10%
(or +/- 0.5 cm) and reproducible to +/- 2 mm ? (y/n/x)
Patient or Operator not exposed to rough edges or other hazards? (y/n)
Operator technique control charts are posted? (y/n)
Operator protected during exposure by adequate radiation shield? (y/n)
Remarks
B4444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444
<F2> = LOOKUP for Codes: <F9> to edit remark

2. Collimation Assessment

The ACR manual requires that the medical physicist test the alignment of the x-ray field with the light field (when a light field is available), the alignment of the x-ray field with the image receptor, and the alignment of the compression paddle with the image receptor (at the chest wall). These tests are to be repeated "... for all available cones and collimators." (p5 1992, p137 1994).

MQSA inspectors are currently required to review the survey report to determine if these tests have been conducted for at least the most frequently used aperture (or cone or collimator) and compression device for each image receptor size (or patient support size) used clinically in the facility. If a variable collimator is used, then the test must be done for at least the collimator setting most frequently used clinically at the facility.

Note. *There is currently some controversy over what tolerance ought to be allowed for alignment of the x-ray field and the image receptor on the right, left, and nipple sides. It is FDA's intent to allow the x-ray field to extend beyond the image receptor; i.e., the film in the cassette, but not beyond the image receptor holder assembly. The amount of tolerance allowed beyond the image receptor is currently under review and has not yet been determined. Therefore, while the test must be done as part of the medical physicist survey, FDA suggests that, at this time, the physicist refrain from making recommendations that corrective action be taken under MQSA, unless the x-ray field*

extends beyond the edge of the patient support on the right, left, and nipple sides, or extends more than 2% of the SID beyond the chest wall edge of the image receptor.

Inspection questions and entries relating to collimation assessment are listed in screen #4 below:

Screen #4

?4444444444444444444 **Survey Report/Collimation** 4444444444444444444444444444@

	Done?	**Pass/Fail Given?**
X-Ray Field - Light Field	(y/n/p/x)	(y/n/x)
X-Ray Field - Image Receptor Alignment	(y/n/p)	(y/n/x)
Compression Device Edge Alignment	(y/n/p)	(y/n/x)

Remarks

B4444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444

<F2> = LOOKUP for Codes: <F9> to edit remark.

3. Focal Spot Size

The ACR manual requires that the size of the focal spot be measured (using a slit camera or a star pattern in the 1992 manual, and a slit camera or that the limiting resolution of the system be determined using a high contrast resolution pattern in the 1994 manual). The manual requires (p11 1992, p143 1994) that "...a kVp setting commonly used for mammographic imaging and the highest mA station available..." should be used and that "an exposure time to produce a film optical density between 0.80 and 1.20" should be selected. Further, the manual requires that the test be repeated for an additional focal spot size if available (Procedure Step 14, both manuals) and states that the test "...may be repeated at other kVp and mA settings if the dependence...is of concern." (Procedure Step 15, both manuals).

MQSA inspectors are currently required to review the survey report to determine if the test was done for all focal spots that are used clinically and that numerical results are provided to the facility. The other issues relating to how the test was conducted are NOT evaluated.

Inspection questions and entries relating to the focal spot size test are listed in screen #5 below:

Screen #5

?4444444 **Focal Spot Size/Resolution Measurement** 444444@

Done?	(y/n)
Done for all clinically used focal spots?	(y/n/x)
Numerical results given?	(y/n/x)
Pass/fail given?	(y/n/x)

Remarks

B4444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444A

<F2> = LOOKUP for Codes: <F9> to edit remark.

4. kVp Accuracy and Reproducibility

The ACR manual requires that the medical physicist conduct these tests in the manual mode, using four exposures at "... the kVp at which the system is normally used clinically..." and that these tests be repeated "...at other clinically important kVp's..."(p16 1992, p147 1994).

MQSA inspectors are currently required to review the survey report to determine if the medical physicist tested the kVp **accuracy** at all clinically important kVp's and that numerical results are provided to the facility. This is interpreted to mean at the kVp normally used clinically at the facility (the most commonly used kVp) and, if other kVp's are used clinically, at up to two other kVp's. These additional kVp's are selected at the discretion of the medical physicist.

Inspection questions and entries relating to the kVp accuracy are listed in screen #6 below:

Screen #6

4444444444 **kVp Accuracy** 44444444444444444444444444
Done? (y/n)
Done at all clinically important kVps? (y/n/x)
Numerical results given? (y/n/x)
Pass/fail given? (y/n/x)
Remarks
B4444444444444444444444444444444444444444444444444444A
<F2> = LOOKUP for Codes: <F9> to edit remark.

MQSA inspectors are currently required to review the survey report to determine if the medical physicist tested the kVp **reproducibility** at least at the kVp at which the system is normally used clinically at the facility (the most commonly used kVp) and that numerical results are provided. The specifics of the exposure conditions are NOT evaluated.

Inspection questions and entries relating to kVp reproducibility are listed in screen #7 below:

Screen #7

?4444444444 **kVp Reproducibility** 4444444444444444444444
Done? (y/n)
Done at the kVp normally used clinically? (y/n/x)
Numerical Results given? (y/n/x)
Pass/fail given? (y/n/x)
Remarks
B4444444444444444444444444444444444444444444444444444A
<F2> = LOOKUP for Codes: <F9> to edit remark.

5. Beam Quality (HVL) Measurement

The ACR manual (pp17-18 1992, pp148-149 1994) requires that the medical physicist test the beam quality or HVL using a specific exposure geometry (including collimation of the x-ray beam) for the kVp at which the system is normally used clinically and that the test be repeated "...for other kVp settings ranging from the lowest to the highest used clinically."

MQSA inspectors are currently required to review the survey report to determine if the medical physicist did this test at least at the kVp at which the system is normally used clinically in the facility (the most commonly used kVp) and that numerical results are provided to the facility. The specifics of the exposure conditions are NOT evaluated. Inspection questions and entries relating to HVL measurement are listed in screen #8 below:

Screen #8

?4444**Beam Quality (HVL) Measurement**4444444444@
Done? (y/n)
Done at the kVp normally used clinically? (y/n/x)
Numerical results given? (y/n/x)
Pass/fail given? (y/n/x)
Remarks
B4444444444444444444444444444444444444444444444444444A
<F2> = LOOKUP for Codes: <F9> to edit remark.

6. AEC System Performance Assessment

The ACR Manual requires that the medical physicist test a variety of features of the AEC. In particular the reproducibility, performance capability (including kVp and thickness tracking) and density control function must be tested.

a. Reproducibility

The manual requires that specific exposure conditions be used (pp20-21 1992, pp159-162 1994; i.e., part of test #8) including a kVp "routinely used for the selected imaging mode"(1992), or "normally used clinically" (1994) and a 4-cm phantom (1992) or RMI 156 or equivalent (1994), that four exposures be taken and that the test be done in terms of mAs and optical density (1992) or mAs and exposure (1994).

MQSA inspectors are currently required to review the survey report to determine if the medical physicist conducted the test at the kVp normally used clinically at the facility (the most commonly used kVp) and that numerical results are provided to the facility.

Inspection questions and entries relating to AEC performance/reproducibility test are listed in screen #9 below:

Screen #9

?444**AEC Performance/Reproducibility**444444444444444@
Done? (y/n)
Done at the kVp normally used clinically? (y/n/x)
Numerical results given? (y/n/x)
Pass/fail given? (y/n/x)
Remarks
B4444444444444444444444444444444444444444444444444444444A
<F2> = LOOKUP for Codes: <F9> to edit remark.

b. Performance Capability

For kVp tracking, the manual requires that specific exposure conditions be used and that the test be done in terms of optical density. The test is to be done using "...the lowest kVp used clinically..." (pp21 1992, pp151-152 1994) and then repeated "..for all other kVp's used clinically" (1992) or for "..a range of kVp's which are normally used clinically..." (1994). The test is then to be repeated for "other imaging modes...which are used clinically."

MQSA inspectors are currently required to review the survey report to determine if the medical physicist conducted the test in terms of optical density, used a typical phantom thickness (or 4 cm), selected up to three kVp values that are used clinically by the facility, and that numerical results are provided to the facility. If only one kVp is used clinically, this part of the AEC test need not be done. If only two kVp's are used clinically, these two kVp's must be tested. If more than two kVp's are used clinically, then three kVp's must be selected by the physicist and used for this test.

For thickness tracking, the manual requires that specific exposure conditions be used and that the test be done in terms of optical density. The test is to be done, according to the 1992 manual (p21), using "the kilovoltage routinely used for the selected imaging mode" and phantom thicknesses of 2 cm, 4 cm and 6 cm and repeated "for all other kVp's which are normally used clinically." According to the 1994 manual (pp151-152), the test is conducted using "...phantom thicknesses of 2 cm, 4 cm, and 6 cm and the kVp setting(s) used routinely in clinical practice for those breast thicknesses ..."

MQSA inspectors are currently required to review the survey report to determine if the medical physicist conducted the test in terms of optical density, using phantom thicknesses of 2 cm, 4 cm, and 6 cm and at least the kVp setting(s) used routinely in clinical practice for those breast thicknesses, and that numerical results are provided to the facility.

Inspection questions and entries relating to AEC performance capability are listed in screen #10 below:

Screen #10

?444444444444**AEC Performance/Tracking**4444444444444444@
Done? (y/n)
Done at typical thickness (or 4 cm) for 3 kVps? (y/n/x)
Done for 2, 4 and 6 cm at typical kVp(s)? (y/n/x)
Results given as optical densities (y/n/x)
Numerical results given? (y/n/x)
Pass/fail given? (y/n/x)
Remarks
B4444444444444444444444444444444444444444444444444444444444444A
<F2> = LOOKUP for Codes: <F9> to edit remark.

c. Density Control Function

The manual requires that specific exposure conditions be used and that the test be done in terms of optical density. The test is to be done using the most routinely used kVp and for each "available setting of the AEC system's density control selector" (p22 1992, p152 1994).

MQSA inspectors are currently required to review the survey report to determine if the medical physicist conducted the test for all the density control settings used clinically in the facility or, if more than three settings on either side of the normal setting are used, then the normal and at least three settings on either side of normal.

Inspection questions and entries relating to AEC performance/density control function are listed in screen #11 below:

Screen #11

?4**AEC Performance/Density Control**444@
Done? (y/n)
Pass/fail given? (y/n/x)
Remarks
B4444444444444444444444444444444444444444444A
<F2> = LOOKUP for Codes: <F9> to edit remark.

7. Uniformity of Screen Speed

The ACR manual requires that the medical physicist test each mammography cassette (pp25-26 1992, pp156-157 1994) using "...the imaging mode and kVp most commonly used for clinical examinations..." with a 4-cm phantom and a technique selected to produce "an image optical density in the range of 1.10 to 1.50..." in the 1992 manual or "an image optical density greater than 1.20..." in the 1994 manual.

MQSA inspectors are currently required to review the survey report to determine if the medical physicist conducted the test and provided numerical results to the facility. The specifics of the exposure conditions are NOT evaluated.

Inspection questions relating to the uniformity of screen speed test are listed in screen #12 below:

Screen #12

?44**Uniformity of Screen Speed**4444@
Done? (y/n)
Numerical results given? (y/n/x)
Pass/fail given? (y/n/x)
Remarks
B4444444444444444444444444444444444A
<F2> = LOOKUP for Codes: <F9> to edit remark.

8. Breast Entrance Exposure and Average Glandular Dose

The ACR manual requires that the medical physicist perform this test using specific exposure conditions, a specific mammographic phantom (RMI 156 or equivalent), and "..the kVp at which the system is normally used clinically." The test is then to be repeated "...until a total of four exposures have been recorded" (pp27-28 1992, pp159-162 1994) and then repeated "... at other clinically utilized kVp's (1992) or other target/filter combinations and kVp's (1994)..."

MQSA inspectors are currently required to review the survey report to determine if the medical physicist conducted the test at the kVp normally used clinically (the same as that used for the HVL test) with the appropriate phantom and provided numerical results to the facility. The other specifics of the exposure conditions are NOT evaluated.

Inspection questions relating to the average glandular dose test are listed in screen #13 below:

Screen #13

?44444444**Average Glandular Dose**4444444444@
Done? (y/n)
Exp. & HVL at same clinical kVp? (y/n/u)
RMI156 or equivalent phantom? (y/n/u)
Numerical Results given? (y/n/x)
Pass/fail given? (y/n/x)
Remarks
B4444444444444444444444444444444444444444444444A
<F2> = LOOKUP for Codes: <F9> to edit remark.

9. Image Quality Evaluation

The ACR manual requires that the medical physicist perform this test using specific exposure conditions, a specific mammographic phantom (RMI 156 or equivalent), and "..the kVp and

density control settings used clinically for a breast of thickness and density corresponding to the phantom." (pp32-33 1992, pp166-167 1994). The image is then to be scored using the specific technique and scoring method detailed in the manual.

MQSA inspectors are currently required to review the survey report to determine if the medical physicist conducted the test at the clinical kVp appropriate for a 4.0- to 4.5-cm-thick breast with a 50/50 composition, with the appropriate phantom and provided numerical results (three object scores) to the facility. The other specifics of the exposure conditions are NOT evaluated.

Inspection questions relating to the phantom image quality test are listed in screen #14 below:

Screen #14

?4444444**Phantom Image**4444444444444444444444444@
Done? (y/n)
Done at the kVp normally used clinically? (y/n/x)
3 object scores given? (y/n/x)
Pass/fail given? (y/n/x)
Remarks
B4444444444444444444444444444444444444444444444444A
<F2> = LOOKUP for Codes: <F9> to edit remark.

10. Artifact Evaluation

The ACR manual requires the medical physicist to conduct this test using "technique factors normally used clinically, choosing the lowest kVp used clinically..." and using a specified phantom. The test requires that two images be made using the same cassette and processed orthogonally. The test is to be repeated "for other image receptor sizes...and for all available focal spot sizes and filters used clinically" (pp37-38 1992, pp171-172 1994).

MQSA inspectors are currently required to review the survey report to determine if the medical physicist conducted the test. The specifics of the exposure conditions are NOT evaluated.

Inspection questions and entries relating to the artifact evaluation test are listed in screen #15 below:

Screen #15

?4444**Artifact Evaluation**4444444@
Done? (y/n/p)
Pass/fail given? (y/n/x)
Remarks
B4444444444444444444444444444444A
<F2> = LOOKUP for Codes: <F9> to edit remark.

X-RAY UNITS WITH MULTIPLE TARGET-FILTER COMBINATIONS

Some of the newer x-ray units with multiple targets and filters and varying automatic modes (such as GE's DMR and Siemens Mammomat 3000) present the user with new capabilities and call for additional testing.

If the above 10 QC tests are repeated for all target-filter combinations available for the unit besides Mo-Mo, the additional tests will increase the survey cost considerably. Furthermore, some tests are generator-specific and some correspond to technique factors that are not used in a clinical setting. Under the current Interim Regulations, MQSA inspectors will assess only the "required" tests. They will not assess any "recommended" tests.

a. Required Tests

Under the current Interim Regulations, the only additional tests FDA requires are those listed in the ACR QC manuals (either the 1992 or the 1994 version), which were adopted by reference. Although the 1994 manual states that several tests be repeated, the 1992 manual states that only the artifact test be repeated (and then only for alternative filters). Thus, the artifact test is the only additional test that is actually required at this time for clinically used filters other than molybdenum.

b. Recommended Tests

FDA is not currently recommending that all tests be repeated routinely for target-filter combinations other than the one normally used in a clinical setting. However, based on manufacturers' input and feedback from many in the physics community, FDA does recommend the set of tests listed below as the minimum good practice standard for testing such machines. This recommendation assumes that the combination tested is being used clinically at the facility in addition to the **Mo-Mo** combination, which is assumed to be used most of the time.

Therefore, in addition to the 10 QC tests that the physicist is required to perform with Mo-Mo, FDA specifically recommends that the tests listed below be repeated for **alternative filters** such as rhodium or other filters.

- Beam Quality (HVL measurement)
- Artifact Evaluation

Also, for **alternative targets,** such as rhodium and tungsten when used with other filters such as rhodium (e.g., **Rh-Rh** and **W-Rh)**, the following set is recommended:

- Collimation Assessment
- Focal Spot Size / Resolution Measurement
- Beam Quality (HVL measurement)
- AEC Performance Assessment, performance capability (only for 6-8 cm phantoms and with appropriate kVp's)
- Artifact Evaluation (only if not done with Mo-Rh)

THE MEDICAL PHYSICIST QUALIFICATIONS UNDER MQSA

Medical physicists performing mammography surveys must meet the following specific requirements (see §900.12(a)(3)):

a. Each medical physicist must have a State License, State Approval, or Certification in an acceptable specialty area by an FDA-approved body*.

** **Note.** The bodies approved to certify medical physicists are the American Board of Radiology (ABR) (either in diagnostic or radiological physics), or the American Board of Medical Physics (ABMP) (in diagnostic imaging physics).*

For MQSA purposes, a medical physicist approved or licensed in one State is considered qualified to conduct MQSA surveys in any State. However, States other than the State of approval may have their own State requirements that the physicist must meet in order to practice in that State.

Acceptable documentation to establish that a medical physicist has a State license or board certificate would be a copy of the license or certificate, a pocket card, or a letter from the State or FDA-approved organization (bearing the organization's letterhead) stating that the physicist is licensed or certified. Acceptable documentation for State approval is a letter or other document from the State showing the same. **OR**:

b. A physicist who is **not approved, licensed, or certified** (such as a new graduate or any individual with the appropriate degree as described below) may qualify to perform mammography surveys under MQSA **until 10/27/97,** if he/she has the following education, training, and experience:

(1) A masters or higher degree in physics, medical physics, radiological physics, applied physics, biophysics, health physics, engineering, radiation science, or in public health with a bachelor's degree in the physical sciences; **AND**

(2) 1 year training (see 1st. bullet on the following page) in medical physics specific to diagnostic radiology ; **AND**

(3) 2 years experience (see second bullet on the following page) in conducting performance evaluations of mammographic equipment.

Note. *After October 27, 1997, qualification under option "b" above, no longer applies.*

Acceptable documentation to establish qualification (1) above must indicate that the physicist has the appropriate degree, including the name of the institution or educational organization, the date of degree, and the subject area in which the degree was awarded. A copy of the degree or a letter from the institution that awarded the degree is acceptable.

Based on experience since passage of MQSA, FDA has determined that

- Thirty (30) semester* hours in medical physics, or their equivalent in CME or on-the-job** training establishes that a medical physicist has adequate training to satisfy requirement (2) above. A lesser amount would have to be evaluated by FDA on a case-by-case basis.

  * The 30 semester hours of academic training refers to course materials related to diagnostic radiological physics and need not be limited to courses with medical physics in their titles. Courses in instrumentation, radiation measurements, x-ray theory, quality assurance, and so forth would also qualify. Credits for independent study or research would also count as part of this training. A person with a masters degree or higher in medical physics is considered to satisfy this training requirement without having to provide additional documentation. A person with a masters degree in the other areas listed under requirement (1) above will have to show that he/she has the appropriate training. For comparison purposes, FDA equates one semester hour to ten contact hours of continuing education training.

  ** On-the-job training must be organized formal training presented by qualified individuals. Documentation indicating the subjects taught, the date and duration of training, and the name of the instructor must be available for MQSA inspections.

  A combination of academic training, CMEs, and on-the-job training which adds up to 1 year of training is also acceptable as meeting requirement (2) above. An example would be 20 semester hours, 50 CME, and 2 months of on-the-job training.

- The survey of 20 or more mammography x-ray units (including evaluation of the technologist's QC tests) establishes that the medical physicist has adequate experience to satisfy qualification (3) above. The period of time over which 20 surveys are done is open. A fewer number of units surveyed would have to be evaluated by FDA on a case-by-case basis. Similarly, 2 years experience in a single facility with a few mammography machines may not by itself be sufficient to satisfy qualification (3) above and would have to be evaluated on a case-by-case basis.

Acceptable documentation to establish experience may be a written statement by the physicist's supervisor or the management of the facility (s) surveyed indicating that the physicist performed at least the required number of surveys.

Note. *If* ***documentation*** *is not available for (b.2) or (b.3) above, proper* ***attestation*** *(see the attestation form at the end of this document) by the medical physicist will be acceptable only for training or experience gained prior to October 1, 1994.* **AND:**

c. All medical physicists must participate in continuing education programs related to mammography, either by teaching or completing an average of at least 5 continuing education or medical education units (CEU's or CME's) per year.

Note*. The five continuing education credits per year is an average. The starting date of the averaging period is the later of October 1, 1994 or the date the physicist met the requirements in* ***a.*** *or* ***b.*** *above. For example, if the physicist earned 9 credits during the first year after his/her starting date, 6 credits during the second year, and 0 credits during the third year, he/she would have met the requirements for the first three years.*

Examples of acceptable documentation for continuing education credits include a certificate, letter, or other documents from the training provider indicating the amount, subject, and successful completion of the course or training.

Inspection questions and entries relating to the medical physicist's qualifications are listed in screen #16 below:

Screen #16

M P R I S

Inspection **E**quip. **R**egistration **R**eports **U**tility **Q**uit

?4444444444444**Medical Physicist's Qualifications**4444444444444444444@

Name Dennis xxx, M.S.

Certified?	(y/n/c)	Type of Certif.? (A/B/O)(code)	(OR)
State licensed ?	(y/n/c)	State of License (code)	(OR)
State approved ?	(y/n/c)	State of Approval? (code)	(OR)
M.S. or Ph.D.?	(y/n/c)	(Phy., Med. Phy., Hlth.Phy, Rad.Phy., Appl. Phy., Biophy., Eng., Rad.Sci.)	(OR)

M.S.(Public Health) & B.A./B.S. (Physical Science)? (y/n/c) (AND)

Training adequate?	(y/n/c)
(AND)	
Mammo. experience adequate?	(y/n/c)
Date completed initial requirements	mm/dd/yy
Average CME credits/year adequate?	(y/n/c/x)

Remarks:

B4444444444444444444444444444444444444444444444444444444444444444444444444444A

<F9> to edit remark.

Note: *the code for certification is as follows:*

A*: American Board of Radiology (ABR)*

B*: American Board of Medical Physics*

O*: Other*

ATTESTATION FORM

Regarding Requirements of The Mammography Quality Standards Act

Attestation must include as much of the following information as possible:

Name of the institution/facility where the applicable training or mammography reading/interpreting, or other activity, took place; name of the course(s) or training (where applicable); the attendance, reading/interpreting, or other activity dates; and the supervising/responsible person (where applicable) for the institution/facility. Please provide these details in the space below. Attach additional sheets if necessary.

I _____ attest that, to the best of my knowledge and my belief, the following information provided in this declaration is true and correct. I understand that FDA may request additional information to substantiate the statements made in this declaration:

_____
_____
_____
_____
_____
_____
_____

I understand that knowingly providing false information in a matter within the jurisdiction of an agency of the United States could result in criminal liability, punishable by up to $10,000 fine and imprisonment of up to five years, or civil liability under the MQSA, or both.

_____
Attestor's Signature and Title

_____
Date signed

Facility Name and Address (if applicable):
(including zip code) _____
_____
_____

Facility ID Number (if applicable)
(from the Facility's MQSA certificate) _____